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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/428,203

Filing Date: October 27, 1999

Appellants: OKUNJI ET AL.

Abanti A. Bhattacharyya
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 14, 2011 appealing from the Office action mailed June 3, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
Claims 1, 11, 30 and 38.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Kapundu, M. et al. "New Triterpenoids from *Napoleonea imperialis*" [Triterpenoïdes nouveaux de *Napoleonaea imperialis*]. PTO 10-0557. Translated by: The McElroy Translation Company, November 2009, pp. 1-19.

Kapundu, M et al. "Triterpenoïdes nouveaux de *Napoleonae imperialis*".
Phytochemistry, vol. 19, no, 15 (1980), pp. 6154-622.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, 30 and 38 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kapundu et al. (Translation of Kapundu et al. relied upon herein.).

The claims are drawn to a biologically active extract comprising a fractionated extract from *Napoleonaea imperialis*, wherein said extract is obtained using an organic solvent; and wherein said biologically active extract is saponin-enriched and exhibits therapeutic anti-leishmanial activity. The claims are further drawn to a biologically active extract according to claim 1, wherein said extract is obtained directly from solvent extraction of powdered seeds of *Napoleonaea imperialis* utilizing said solvent. The claims are further drawn to a biologically active extract according to claim 1, wherein said solvent is methanol, and wherein said extract is obtained directly from solvent extraction of powdered seeds of said plant utilizing said solvent. The claims are further drawn to a biologically active extract according to claim 11, wherein said solvent is methanol.

Kapundu teaches a methanol extract from powdered seeds of *Napoleonaea imperialis*, comprising page 615, Column 2, lines 11-12. Kapundu. The methanol powdered seed extract comprises saponin. However, the claim-designated functional effect is considered inherent to the extract taught by Kapundu because the source of the plant, the particular plant material from the source plant, and the solvent used in the making of the plant extract taught by Kapundu are one and the same claimed by Appellants. Therefore, a biologically active saponin-enriched extract comprising a fractionated methanol extract from powdered seeds of *Napoleonaea imperialis*, which exhibits therapeutic anti-leishmanial activity is deemed inherent to the Kapundu' extract.

The reference anticipates the claimed subject matter.

(10) Response to Argument

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102(b), a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 266 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose each limitation of the claimed invention, *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the functions of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Appellants' discussion of the prosecution history related to this application, as set forth under "VII. ARGUMENT", is noted by the Examiner.

In section "(A)" of the Appeal Brief entitled "Are claims 1, 11, 30, and 38 unpatentable as being anticipated by Kapundu et al. because Kapundu et al. "inherently" discloses each limitation of the claimed invention by functioning in accordance with, or include the claim limitations even though Kapundu does not expressly teach "a biologically active extraction comprising a fractionated extract from *Napoleonaea imperialis*, exhibiting anti-leishmanial activity?", Appellants argue case law. Appellants' main argument is directed to the idea that "The Examiner likely believes that her inherency argument is supported by Kapundu et al's teaching of an intermediate methanolic extraction step. However, the present Appellants are not claiming a new property or use of a previously known composition. Rather, the present Appellants recite a direct methanolic extraction of the powdered seeds of *N. imperialis* as it is shown to provide a unique composition that is effective in the treatment of a debilitating disease, leishmania, similar to the purity standard established by Sanofi-Aventis." Appellants contend that the totality of Kapundu provides a myriad list of possible compounds. Thereby, Appellants conclude Kapundu cannot provide the necessary technical reasoning to reasonably support the alleged inherent characteristics flows from the teaching of the prior art.

The Examiner has carefully considered Appellants' position that Kapundu' fails to teach the claimed invention. However, Kapundu expressly teaches a fractionated extract from powdered seeds of *Napoleonaea imperialis* seed fraction enriched with saponin, which is prepared using the same ingredients and process steps disclosed by Appellants as being useful in preparing a biologically active extract comprising a

fractionated extract from *Napoleonaea imperialis*, wherein the biologically active extract is saponin-enriched and exhibits therapeutic anti-leishmanial activity. See page 3 of the translated reference, under "RESULTS AND DISCUSSION", wherein Kapundu teaches extracting seeds of *Napoleonaea imperialis* with methanol. While Kapundu does teach identification of compounds contained therein the methanolic seed extract, thus necessitating a hydrolysis step of the extract, such disclosure by Kapundu does not negate the fact that the prior art teaches the claimed composition. Thus, while Kapundu does not expressly teach that the prior art methanolic plant extract has the claimed biological activity *per se*, the biological activity is inherent to the Kapundu' composition because the source of the plant, the particular plant material from the source plant, and the solvent used in the making of the plant extract taught by Kapundu are one and the same as instantly claimed by Appellant. Therefore, anti-leishmanial activity is inherent to the Kapundu' saponin-enriched extract obtained by direct solvent extraction of powdered seeds of *Napoleonaea imperialis* using methanol, absent evidence to the contrary.

In Section "(B)" of the Appeal Brief entitled "Has the Examiner erred in applying the "inherency" doctrine in a final rejection of Appellants' claims 1, 11, 30, and 38 as being anticipated by Kapundu et al?", Appellants' main argument is directed to the idea that the Examiner has misapplied the inherency doctrine. Appellants' summary of the most relevant portions of the prosecutor history of the instant application and associated rebuttals with regard to Kapundu is noted by the Examiner. Appellants further argue

that the teachings of Kapundu [are] strictly dependent upon the hydrolyzed seed extracts of *N. imperialis*'. Appellants argue the pursuit of 'only naturally occurring pharmacologically active compounds . . . rather than hydrolyzed products . . . present knowledge on *N. imperialis* indicated that the major constituents of this plant are saponins . . . saponin contents have been reported to vary depending on factors (discussing geographic location) . . . saponin distribution among the organs of a plant may vary considerably (citing as example the variation in saponin concentration in marigold flowers varies significantly from that of the roots) . . . Our work on Dracaena species revealed that vary [very] high saponin content are found mostly in the seeds."

See Christopher O. Okunji Rule §1.132 affidavit at 6 (June 4, 2004). Note also that Appellants specifically discuss the problems associated with hydrolysis of saponins as taught by Kapundu, et al. These include complications with artifact formation, low yields, low selectivity and difficulty with structure elucidation. See id at 8.'

Appellants' arguments have been fully considered. However, they are neither persuasive nor commensurate in scope to the limitations of the claimed invention. Respectfully, it is irrelevant that Kapundu teaches identification and elucidation of compounds resulting from the hydrolysis of the saponins obtained by direct extraction of saponins from the seeds of *N. imperialis* using methanol. Nevertheless, again, Appellants urge, "As required by the MPEP § 2112, there must be a basis in fact and/or technical reasoning to reasonably support that the allegedly inherent characteristic flows from the teachings of the prior art." Thereby, Appellants misread the disclosure at page 15 of Kapundu et al. (translated document) to establish that 'no such factual basis is

formulated by the Examiner because one cannot find such a teaching' in the prior art reference. The Examiner is not persuaded. Contrary, to Appellants, Kapundu teaches use of diethyl ether, *i.e.*, Et₂O, instead of ethanol. For instance, Kapundu discloses, "250 g of ground seeds of *Napoleonaea imperialis* are extracted at reflux for 3 h with 2.5 L of 80% MeOH. The extract is brought to dryness under reduced pressure. The residue is dissolved in MeOH, and then filtered on a Buchner. The addition of a quintuple volume of Et₂O to the filtrate precipitates the saponin, which is separated by filtration, then dried. Saponin is redissolved in MeOH to be again precipitated by Et₂O. The operation is repeated until a colorless powder is obtained. 250 g of seeds gave 14 g of saponin." See page 15, under "EXPERIMENTAL PART: Extraction of the saponin", of the translated document of Kapundu et al. Also, see page 15, lines 17-24, of the present application, wherein Appellants disclose using one and the same plant ingredient, solvent, and process steps taught by Kapundu in extracting saponin from the claim-designated plant material. Given that Kapundu teaches a product-by-process composition prepared from one and the same plant source material, solvent and experimental processing conditions (namely direct methanol extraction of the powdered seeds of *N. imperialis*) disclosed by Appellant as being useful in preparing a biologically active extract comprising a fractionated extract from *Napoleonaea imperialis* enriched in saponins and exhibiting therapeutic anti-leishmanial activity, it is considered that the claim-designated functional effect of anti-leishmanial activity is inherent to the Kapundu' composition.

Based on the foregoing, the Office believes that the anticipatory rejection based on inherency is proper given that Appellant has not provided a clear and convincing argument that the instantly claimed product-by-process is an act of invention rather than mere observation.

In Section "(C)" of the Appeal Brief entitled "Is the term "fractionated" as recited in claim 1 sufficiently outside the scope of the term "fractionating" to support the Examiner's position that it provides sufficient grounds for requiring an additional search leading to the final rejection of claims 1, 11, 30, and 38 in the Examiner's Action of June 4, 2010"; and, in In Section "(D)" of the Appeal Brief entitled "Is the Examiner's reopening of prosecution to enter an amendment and finally rejecting the claims after submission of an Appeal Brief proper under MPEP § 1207.04 when: (i) The action is used to reapply a reference raised by the Examiner in previous office actions and omitted in subsequent Office actions; and (ii) Does the omission of the reference in subsequent Office actions and a telephonic interview indicating allowability "absent the discovery of prior art that reads on the claimed invention" act as an implied waiver of the requirement under MPEP 707.07(e) (Noting All Outstanding Requirements) and MPEP 704.10 (Waiver of the Requirement)?", Appellants' arguments are directed to issues that are not appealable. Therefore, the Examiner has no comment on the summary of issues set forth contained under these sections in the brief.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michele Flood/

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/Terry A McKelvey/

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